

AUG - 4 1997

Meeting Log

Subject : Immunotoxicity Working Group

Site: EPA

Date : July 29, 1997

Log Entry Source: Susan Aitken *zef*

Commission Attendees: Susan Aitken

CPSA 6 (b)(1) Cleared
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The purpose of this meeting was to develop a set of general guidelines adhering to general ICCVAM guidelines but addressing the specific information and questions needed by a peer review panel in immunotoxicity testing. The Local Lymph Node Assay (LLNA) is the first immunotoxicity test method submitted for validation to ICCVAM.

Specific Items:

1. General review of ICCVAM process
2. Formulate questions to test sponsor
 - a) Discussion of various regulatory agency guidelines for immunotoxicity testing
 - b) Question of implications of ICCVAM approval of one specific method when some others may be equally acceptable but have not yet been submitted for ICCVAM review; will this essentially drive the alternatives off the marketplace in contracting for regulatory testing? Decision to evaluate alternative tests separately on basis of scientific information submitted, not on implications of acceptance.
 - c) Brainstorming session to develop a list of specific questions that peer review panel should ask (e.g. threshold, range evaluated, strain of mouse, protocol changes, comparison with guinea pig results, robustness of test, blinded studies?, actual # of animals used if two-tier testing is needed, need for summary vs. raw data, etc.).
3. Peer review panel nominations to be done by email to chair and to be discussed at the next meeting, probably the beginning of September.

NN